

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

|  |   |   |
|--|---|---|
| Applicant's or agent's file reference<br>MLC/LCW/2874PC  | <b>FOR FURTHER ACTION</b>   | See item 4 below  |
| International application No.<br>PCT/GB2006/003416   | International filing date ( <i>day/month/year</i> )<br>15 September 2006 (15.09.2006) | Priority date ( <i>day/month/year</i> )<br>15 September 2005 (15.09.2005) |
| International Patent Classification (8th edition unless older edition indicated)<br>See relevant information in Form PCT/ISA/237 |   |   |
| Applicant<br>SMITH & NEPHEW, PLC   |   |   |

|                                     |  |   |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
|-------------------------------------|--|---|-----------|---------------------|-------------------------------------|------------|----------|-------------------------------------|-------------|--|--------------------------|------------|----------------------------|-------------------------------------|-----------|---|--------------------------|------------|-------------------------|--------------------------|-------------|--|--------------------------|--------------|---|
| 1.                                  | This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 <i>bis</i> .1(a).  |   |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| 2.                                  | This REPORT consists of a total of 11 sheets, including this cover sheet.<br><br>In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.   |   |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| 3.                                  | <p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 60%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> | <input checked="" type="checkbox"/>   | Box No. I | Basis of the report | <input checked="" type="checkbox"/> | Box No. II | Priority | <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> | Box No. I  | Basis of the report   |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input checked="" type="checkbox"/> | Box No. II   | Priority  |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input checked="" type="checkbox"/> | Box No. V  | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| <input type="checkbox"/>            | Box No. VIII   | Certain observations on the international application   |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |
| 4.                                  | The International Bureau will communicate this report to designated Offices in accordance with Rules 44 <i>bis</i> .3(c) and 93 <i>bis</i> .1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44 <i>bis</i> .2).   |   |           |                     |                                     |            |          |                                     |             |  |                          |            |                            |                                     |           |   |                          |            |                         |                          |             |  |                          |              |   |

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|---|--|---|--|
| The International Bureau of WIPO<br>34, chemin des Colombettes<br>1211 Geneva 20, Switzerland<br><br>Facsimile No. +41 22 338 82 70 | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;">Date of issuance of this report<br/>18 March 2008 (18.03.2008)</td> </tr> <tr> <td style="padding: 5px;">           Authorized officer<br/><br/> <div style="text-align: center; font-weight: bold;">Dorothee Mülhausen</div> </td> </tr> </table> e-mail: pt01.pct@wipo.int | Date of issuance of this report<br>18 March 2008 (18.03.2008) | Authorized officer<br><br><div style="text-align: center; font-weight: bold;">Dorothee Mülhausen</div> |
| Date of issuance of this report<br>18 March 2008 (18.03.2008)   |  |   |  |
| Authorized officer<br><br><div style="text-align: center; font-weight: bold;">Dorothee Mülhausen</div>                              |  |   |  |

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/GB2006/003416

International filing date (day/month/year)  
15.09.2006

Priority date (day/month/year)  
15.09.2005

International Patent Classification (IPC) or both national classification and IPC  
INV. A61M27/00 A61M1/00 A61M1/14 A61M1/16 B01D61/00 B01D71/00

Applicant  
SMITH & NEPHEW, PLC

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

Name and mailing address of the ISA:



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D-10958 Berlin  
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Date of completion of  
this opinion

see form  
PCT/ISA/210

Authorized Officer

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Telephone No. +49 30 25901-561



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2006/003416

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of:
  - ☒ the international application in the language in which it was filed
  - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ on paper
    - ☐ in electronic form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in electronic form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. II Priority**

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1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43*bis*.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 27

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

☒ no international search report has been established for the whole application or for said claims Nos. 27

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/GB2006/003416

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**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

|                               |             |      |
|-------------------------------|-------------|------|
| Novelty (N)                   | Yes: Claims | 1-26 |
|                               | No: Claims  |      |
| Inventive step (IS)           | Yes: Claims |      |
|                               | No: Claims  | 1-26 |
| Industrial applicability (IA) | Yes: Claims | 1-26 |
|                               | No: Claims  |      |

2. Citations and explanations

**see separate sheet**

**Re Item III.**

Independent claim 27 is describing a method for treatment of the human body by therapy. The claimed method is therefore not allowable regarding to Rule 67(1) (iv) PCT.

**Re Item V.**

1. Reference is made to the following document:

D1: WO 2004/037334 A (SMITH & NEPHEW [GB]; BLOTT PATRICK LEWIS [GB]; GREENER BRYAN [GB]; HAR) 6 May 2004 (2004-05-06)  
D2: WO 2004/024300 A1 (UNIV MICHIGAN [US]; FISSELL WILLIAM H IV [US]; HUMES DAVID H [US]; ROY) 25 March 2004 (2004-03-25)  
D3: US-A-5 328 614 (MATSUMURA KENNETH N [US]) 12 July 1994 (1994-07-12)  
D4: WO 2005/046761 A (SMITH & NEPHEW [GB]; BLOTT PATRICK LEWIS [GB]; GREENER BRYAN [GB]; HAR) 26 May 2005 (2005-05-26)

2. The present application does not meet the requirements of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

An apparatus for aspirating, irrigating and/or cleansing wounds, characterised in that it comprises (p. 1, l. 3-6; claim 1)  
a) a fluid flow path, comprising

- i) a wound dressing, having a backing layer and at least one inlet pipe for connection to a fluid supply tube, which passes through and/or under the backing layer, and at least one outlet pipe for connection to a fluid offtake tube, which passes through and/or under the backing layer at least one inlet pipe being connected to a fluid recirculation tube, and at least one outlet pipe being connected to a fluid offtake tube (claim 1; Fig. 1); and
- ii) a means for fluid cleansing having at least one inlet port connected to a fluid offtake tube and at least one outlet port connected to a fluid recirculation tube (claim 1; Fig. 1);
- b) a fluid reservoir connected by a second fluid supply tube to an integer of the flow path (optionally or as necessary via means for flow switching between supply and recirculation) (claim 1; Fig. 1);
- c) a device for moving fluid through the wound dressing and means for fluid cleansing, and optionally or as necessary the fluid supply tube; and (claim 1; Fig. 1)
- d) optionally means for bleeding the flowpath, such that fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube (optionally or as necessary via the means for flow switching) and recirculated by the device through the flow path (claim 1; Fig. 1).

The subject-matter of claim 1 therefore differs from this known device in that:

Apparatus with means for fluid cleansing using cells or tissue

The problem to be solved by the present invention may therefore be regarded as

To optimise the removal of toxic substances from aspirated body fluids

However, these features have already been employed for the same purpose in a similar device, see document D2, cp. 1, l. 12-17; p. 8, l. 25 - p. 9, l. 10; p. 18, l. 8 - 26; p. 20; l. 20 - 23; p. 39. It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a device according to document D1, thereby arriving at a device according to

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING  
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/GB2006/003416

claim 1 The subject-matter of claim 1 does therefore not involve an inventive step (Article 33(3) PCT).



3. Dependent claims 2-26 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to inventive step, the reasons being as follows:

- 3.1 Document D1 discloses all additional technical features of claims 2-4, 6-24 and 26:

- Claim 2: backing layer is forming a relatively fluid tight seal (claim 1; 9)
- Claim 3: feedthrough point is forming a relatively fluid tight seal (claim 1; 9)
- Claim 4: conformable wound dressing (claim 1)
- Claim 6: single-phase system (claim 2)
- Claim 7: two-phase system (claim 3)
- Claim 8: integer selectively permeable (claim 4)
- Claim 9: other fluid to remove material (claim 5)
- Claim 10: oxidants; proteases; endotoxins; autoinducer ... (claim 8)
- Claim 11: irrigant fluid may be supplied to fill the flowpath from the fluid reservoir via the fluid supply tube while aspirate fluid is aspirated by a device through the fluid offtake(Fig. 1; 2; 11; 12; 27)
- Claim 12: a) a first device for moving fluid through the wound applied to fluid downstream of and away from the wound dressing, and  
b) a second device for moving fluid through the wound applied to the irrigant in the fluid supply tube upstream of and towards the wound dressing (Fig. 1; 3a-11; 27)
- Claim 13: at least one of means for supply flow regulation (Fig. 1; 3a-11; 27: valves)
- Claim 14: diaphragm pump or a peristaltic pump (p. 28, l. 17 - p. 29, l. 10)
- Claim 15: flow rate is a varied flow rate, either randomly or regularly cyclical (p. 29; p. 45)

- Claim 16: cycles of flow rate have a frequency up to 48 per 24 hours (p. 30: 1-50 1/24h)
- Claim 17: pulses of flow velocity have a frequency of from 1 to 60 per min (p. 28: 2-50 ml/min)
- Claim 18: a parallel flow, radial streaming, spiral streaming, helical streaming, spirohelical streaming or circular streaming (Fig. 1-27: implicitly, because the disclosed device for moving fluid across the wound are the same as disclosed in the application and must therefore have the same flow characteristics)
- Claim 19: aspirating means is also a vacuum means for creating a negative pressure on the area surrounding the wound (p. 46, l. 9-11)
- Claim 20: negative pressure is between about 1,01 and 100,3 kPa (0,01 and 0,99 atmospheres) (p. 30: 0,1-1 atm; 0,25-1 atm)
- Claim 21: backing layer is semi-permeable to allow flow rate of gas through it (p. 10-11: D2 is using the same material for the backing layer as described in the application, therefore the backing layer described in D2 should have the same physical and chemical properties)
- Claim 22: apparatus comprises a wound contact layer (claim 1; 9; Fig. 1-27)
- Claim 23: wound contact layer comprises a material chosen from the group: gauze, foam, a porous material, semi-porous material, semi-permeable material, an elastic or onflatable filler (p. 19-20: foam; p. 65: gauze)
- Claim 24: apparatus is portable (p. 3)
- Claim 26: aspiration and irrigation is either sequential or simultaneous (p. 45 ("... the irrigant and/or the wound exudate passes from the wound dressing ...": and: simultaneously, or: sequential))

- 3.2 Starting from document D1 as closest prior art, the additional features of claim 5 will lead to the following technical problem:

To optimise the removal of toxic substances from aspirated body fluids

However, these features have already been employed for the same purpose in a similar device, see document D2, p. 8, l. 25 - p. 9, l. 10; p. 39. It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a device according to document D1, thereby arriving at a device according to claim 5. The subject-matter of claim 5 does therefore not involve an inventive step (Article 33(3) PCT).

- 3.3 Starting from document D1 as closest prior art, the additional features of claim 25 will lead to the following technical problem:

Finding a way to attach the cell culture to the system

However, these features have already been employed for the same purpose in a similar device, see document D2, p. 14, l. 22- p. 15, l. 2 (e.g. silicon); p. 18, l. 8-26; p. 20, l. 20-23. It would be obvious to the person skilled in the art, namely when the same result is to be achieved, to apply these features with corresponding effect to a device according to document D1, thereby arriving at a device according to claim 25. The subject-matter of claim 25 does therefore not involve an inventive step (Article 33(3) PCT).